material would be reviewed in detail and agreed to meet with Pfizer when the review was completed.

During the August 15 meeting, a number of specific changes in the visual aid were discussed, but not all of the changes that we recommended were reflected in the next draft presented by Pfizer in typewritten form on August 16, 1967, a copy of which I have submitted.[1] Oral tentative acceptance was given by the Division of Anti-Infective Drugs to the revised copy, but it was also pointed out that other FDA approvals would be required.

Senator NELSON. What do you mean by that?

Dr. MINCHEW. That the Division to which this material was submitted and the initial reviewers did not have final approval authority.

Senator NELSON. So the Division of Anti-Infective Drugs gave a tentative oral approval of the proposed promotional advertising with a caveat that the final approval would be required by what other department?

Dr. MINCHEW. If it's promotional labeling or promotional advertising or general advertising, it also is reviewed by the Division of Medical Advertising. Final approval for either a New Drug Application or a supplement to a New Drug Application has been vested in the Office of the Director of the Bureau.

Senator NELSON. Well, at this stage in history, had there been an approval of the NDA?

Dr. MINCHEW. Yes. The monograph had been approved on August 10 and the labeling in the package insert was disapproved. Once the monograph is published in the Federal Register, the company is then free to submit for certification batches of the antibiotic.

Senator NELSON. But we are talking about some promotional material.

Dr. MINCHEW. Right.

Senator NELSON. That has nothing to do—is that right?

Dr. MINCHEW. Yes.

Senator NELSON. So what is the practice? Once there is an approval of the NDA, and they are certified to go into the market, are they required then to submit to you, they are required to meet your standards for the package labeling, but you are talking about some other promotional material, aren't you?

Dr. MINCHEW. Correct.

Senator NELSON. Are they required to submit to you all other types of promotional material for approval?

Mr. GOODRICH. What we are talking about, Senator, as pointed out in the statement, is a visual aid used for detailing. This is a piece of material the company brought in just at the final stages to go over with us, to make sure that this visual aid would be all right.

Senator NELSON. This is after the NDA.

Mr. GOODRICH. That is right. This was after the NDA had been approved for this antibiotic and the visual aid was brought in to be reviewed. They are required under the recordkeeping and reporting provisions to submit to us on a regular basis all of the promotional material used.

[1] See information beginning at p. 3568, infra.